REMARKS

Applicant gratefully acknowledges the Examiner's renumbering of the claims submitted March 14, 2003, and appreciates their entry into the application.

Applicant also notes with appreciation the indication of claims 46-48 as being objected to for depending from a rejected claim, but as containing allowable subject matter.

The drawings stand objected to for lead line informalities in FIGs. 11B-11D and for numbering informalities in FIG. 9. These informalities have been corrected as suggested by the Examiner. A Request for Approval of Drawing Changes accompanies this Reply. No new matter is added.

Claims 45-88 are pending. Claims 46 and 48 are objected to as being informal. Claims 49-88 stand rejected under 35 U.S.C. § 112, 1¶, for failing to comply with the written description requirement. Claim 45 stands rejected under 35 U.S.C. § 102(e) as anticipated by Bao et al. (US 6,224,630). Claims 49-62, 67-71 and 75-88 stand rejected under 35 U.S.C. § 102(b) as anticipated by Bao. Claims 49-64, 67-71 and 75-88 stand rejected under 35 U.S.C. § 102(e) as anticipated by Lambrecht (US 6,425,919). Claim 63 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao in view of Lambrecht. Claims 72-74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao in view of Ferree (US 6,245,107). Claims 65 and 66 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lambrecht in view of Felt (WO 98/20939). Claims 72-74 stand rejected under 35 U.S.C. § 103(a) as being

unpatentable over Lambrecht in view of Ferree. These rejections are respectfully traversed.

Following this amendment, the status of the claims are as follows:

Claims 1-44 and 63 have been canceled.

Claims 45-61 and 64-93 are pending.

Claims 89-93 have been added in this Reply.

Claims 45, 46, 49, 62, and 86-88 have been amended in this Reply.

Formal Amendments

Claim 46 has been amended to strike an extraneous numeral reference ("18") from the claim.

New Claims

The Official Action indicated that claims 46-48 were objected to for depending on a rejected claim, but would be allowable if rewritten in independent form to incorporate the limitations of the parent claim 45. Claim 46 has been so rewritten to form new claim 89, with claims 90 and 91 depending. It is respectfully requested that these claims be allowed.

Newly added claim 92 finds basis in originally filed paragraphs [041] through [044]. Newly added claim 93 finds basis in originally filed paragraph [044]. No new matter has been added.

Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 49-88 for failing to comply with the written description requirement of 35 U.S.C. § 112, 1¶. Each of the Examiner's rejections is addressed in turn below, but from the outset, Applicant respectfully submits that these rejections are not the result of a fair application of the written description standard. The relevant inquiry is whether the application, as of it's filing date, would enable one of ordinary skill in the art to convey with reasonable clarity that Applicant had possession of the invention. *See* Vas-Cath Inc. v. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991), a copy of which is attached. Bearing this in mind, the following are presented for the consideration of the Examiner.

Claim 49: "therapeutically or prophylactically treating"

Certainly, the therapeutic nature of the claimed device is well described. For the Examiner's convenience, Applicant points to the following definition from the *Webster's Ninth New Collegiate Dictionary*:

> **ther a peu tic** 1: of or relating to the treatment of disease or disorders by remedial agents or methods.

Certainly, the specification clearly sets forth a device for treating an aperture in the annulus fibrosus, and is therefore, for at least this reason, therapeutic. *See, e.g.,*¶¶ 010-014.

Further, Applicant points to the following definition from the *American Heritage College Dictionary:*

> **pro phy lac tic** acting to defend against or prevent something, esp. disease; protective.

Again, the specification clearly sets forth a device for preventing reherniation of nuclear material through an aperture in the annulus fibrosus, and is therefore, for at least this reason prophylactic. *See, e.g.,*¶ 015.

There are other physiological reasons for the therapeutic and prophylactic nature of the device claimed, which may include scaffolding and reapproximating functions to mention only two, and therefore the above mentioned features are not exclusive.

It is respectfully submitted that one having ordinary skill in the art would understand this. Having shown that the specification adequately addresses both the therapeutic and prophylactic nature of the claimed device, it is therefore respectfully requested that the rejection under 35 U.S.C. § 112, ¶1, be withdrawn.

Claim 49, 86 and 87: "at least one first (second) dimension"

The specification describes devices which are formed from flexible, resilient materials and therefore deformable along their entire body, which therefore clearly includes the concept of deformability across more than one first dimension, and more than one second dimension. Arguably, the various patch-type embodiments are deformable through an infinite number of device configurations, with varying dimensions before and after delivery. Other embodiments, as set forth in ¶042 of the specification are made, for example, of ePTFE, which is flexible and would allow compression, distortion, bending,

crushing, twisting, and other manipulation which would amount to deformation along multiple dimensions, or axes, simultaneously. It is respectfully submitted that one having ordinary skill in the art would understand this.

Having shown that the specification adequately addresses the multi-dimensional nature of the claimed device, it is therefore respectfully requested that the rejection under 35 U.S.C. § 112, ¶1, be withdrawn.

Claims 49, 86 and 87: "at least as large as said aperture dimension"

Applicant believes that "at least as large as" is a recitation that sets the theoretical lower boundary of the second (or relevant) dimension at a dimension of the aperture. In order to expedite prosecution, Applicant has amended the claim to recite that the second dimension be "larger" than the selected dimension of the aperture, which would encompass all dimensions starting from but not including the exact dimension of the aperture along the selected axis. It is respectfully submitted that one having ordinary skill in the art would understand this.

Having shown that the claims as amended obviate the Examiner's rationale for the rejection, it is respectfully requested that the rejection under 35 U.S.C. § 112, ¶1, be withdrawn.

Claims 55, 56 and 67-69: How "aperture dimension" is defined

Applicant traverses this rejection, and maintains that because the claim is definite, the Examiner's request for a definition for a claim term is inappropriate if the metes and bounds of the claim are clear.

The "aperture dimension" is, in effect, the span of the aperture along a selected axis. The claims use this construct to define the aperture in terms of its shape, size or other spatial geometric aspect to define the device of the claims in conformance to the physiology that the device must therapeutically or prophylactically interface with. The specification deals squarely throughout with a method and device for treating annulus apertures, thus Applicant respectfully submits that the written description requirement has been met. It is respectfully submitted that one having ordinary skill in the art would understand this.

The written description requirement having been met with respect to this limitation, it is respectfully requested that the rejection under 35 U.S.C. § 112, ¶1, be withdrawn.

Claims 58: "polyethylene"

Applicant believes that the use of polyethylene is more than adequately supported by the specification, which recites the use of biocompatible materials such as medical grade biocompatible fabrics, fibers of polymer, or biodegradable polymeric sheets. One of the most often used biocompatible materials is polyethylene, notoriously well known in the art as durable and safe for

implantation. The Examiner's attention is invited to the attached patent to Pease (U.S. 2,671,444), issued in 1951, which depicts a prior art implementation of a biocompatible fabric patch, made of polyethylene.

The written description requirement having been met with respect to this limitation, it is respectfully requested that the rejection under 35 U.S.C. § 112, ¶1, be withdrawn.

Claims 60: "polytetrafluoroethylyene"

Applicant traverses this rejection. As admitted by the Examiner, Applicant has disclosed the use of "expandable polytetrafluoroethylyene," which is PTFE subject to additional processing. This processing alters the *physical* properties of the material (*i.e.,* by creating microscopic pores in the structure of the material), but does not chemically transform the material. It remains PTFE.

In effect, the rejection rests on the proposition that while Applicant has set forth possession of the invention if limited to ePTFE, one having ordinary skill in the art would not with reasonable clarity understand that PTFE could be used. It is respectfully submitted that one having ordinary skill in the art would understand that PTFE is, if not absolutely identical to ePTFE, well within the range of known equivalents in the art. It is respectfully submitted that this rejection be withdrawn.

Claims 72-74: "at least a portion of"

The rejection states that while the specification discloses "a patch of human muscle fascia or any other autograft, allograft or xenograft," this

disclosure is inherently limited to the *entire device* being comprised of these materials. Evidently, the Examiner also believes that the device can only be made of *one* of these materials *exclusively*. Applicant traverses this rejection.

First, the disclosure, as one having ordinary skill in the art would appreciate, does not require the narrow interpretation that the Examiner is arguing. The disclosure broadly states that the device can be fascia or *any other* auto-, allo- or xenograft. Certainly, this disclosure would convey the possibility of the device being formed of a *combination* of these materials. See originally filed ¶ [041] of the specification. This is especially true when the specification explicitly describes in ¶ [057] the use of a biodegradable substrate as disclosed in, for example, U.S. Pat. No. 5,964,807 (Gan at al.). Gan, known in the art, explicitly describes hybrid substrates which include cells harvested from the patient.

The written description requirement having been met with respect to this limitation, it is respectfully requested that the rejection under 35 U.S.C. § 112, ¶1, be withdrawn.

Claim 87: "at least partially"

The rejection sets forth that Applicant never discloses the device only partially being delivered through the aperture. Figure 9 clearly depicts a device where a portion, in this case the upper extension, is within the aperture. Clearly, one having ordinary skill in the art would understand that not the entire device need be delivered through the aperture into the subannular space, but only a portion of the device.

The written description requirement having been met with respect to this limitation, it is respectfully requested that the rejection under 35 U.S.C. § 112, ¶1, be withdrawn.

Claim 87: "at least partially spans"

The rejection states that the disclosure does not disclose the device only partially spanning the aperture. This rejection strikes Applicant as inapposite to the previous rejection under this section, which required that the device be *larger* than the aperture. Clearly, if the device has a dimension *larger* than the aperture dimension along the selected axis, some portion of the device does not span the aperture when the device is deployed (*i.e.* that portion of the device which abuts the subannular surface of the annulus peripheral to the aperture and supporting the portion of the device which spans the aperture).

The written description requirement having been met with respect to this limitation, it is respectfully requested that the rejection under 35 U.S.C. § 112, ¶1, be withdrawn.

Rejection under 35 U.S.C. § 102 [Bao]

As a preliminary matter, the Examiner has rejected one claim of the instant application under §102(e) and other claims under § 102(b) as anticipated by the same reference. The distinction giving rise to the disparity in the treatment of these claims is predicated on the Examiner having designated all of the claims rejected under §102(b) as containing new matter. Applicant presumes

that by "new matter" the Examiner is referring to the subject matter indicated as not being supported by disclosure under the written description requirement of 35 U.S.C. § 112, ¶1, as discussed above.

The rejection, however, appears to treat all claims allegedly lacking written description as being *entirely* composed of new matter. This is simply not the case. The claims were rejected under the written description requirement of 35 U.S.C. § 112, ¶1 for allegedly not containing disclosure related to very specific language describing the extent of certain limitations. Even assuming *arguendo* the written description rejections are proper, which the Applicant respectfully submits they are not, the limited extent of any "new matter" would still not properly permit the wholesale application of Bao to the claims without first separating what was originally disclosed and was "new matter". In this instance, it is respectfully submitted that all rejections under 35 U.S.C. § 112, 1¶, have been overcome, so this point is moot.

The Examiner did not elaborate on the distinction between the treatment of the claims under §102 except to say that most of the claims were new matter and therefore not entitled to any priority. Without a greater understanding of what rationale supports the rejection, Applicant is unable to respond further. Applicant respectfully requests, should the Examiner persist with this rejection, that the extent of any "new matter" deemed to be present be properly delineated vis-à-vis the claims and their respective priorities so that a proper and complete response be prepared.

Rejection under 35 U.S.C. § 102(e)

Claim 45 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Bao (US 6,224,630). This rejection is respectfully traversed.

The rejection states that Bao discloses a spool-shaped embodiment in Col. 7, ll. 62-67, where the tops and bottoms of the spool are connected by a centralized vertical extension. It is noted that this centralized vertical extension connecting the spool top and bottom is coextensive with the aperture.

The claim has been amended to require that the extension, unlike that disclosed by Bao, is non-sealing. Bao discloses a plug, and all of the embodiments in that reference are predicated on the concept of a sealing relationship with the aperture. Applicant's invention does not require the vertical extension to have a *in situ* sealing relationship within the aperture in order to promote healing.

In light of the above, it is respectfully requested that the rejection be withdrawn.

Claims 49-62, 67-71 and 75-88 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bao. Applicant traverses the designation of all material in these claims as containing new matter as discussed above, and therefore respectfully submits that it is error to reject these claims under §102(b) and respectfully requests that the rejection be withdrawn. Notwithstanding, Applicant

will respond to the merits of the rejection, with the understanding that these merits would be identical under §102(e).

The rejection states that the cylindrical plug of Bao, which can be constructed so as to comprise or to form a spool like shape, meets all of the requirements of independent claims 49, 86, 87 and 88. This rejection is respectfully traversed.

The Bao patent discloses plugs. In essence, a plug seals an opening through radial engagement circumferentially in the interior of a hole. Applicant points to the following definition from the *American Heritage College Dictionary:*

> **plug** 1. an object, such as a cork, used to fill a hole tightly; a stopper.

The specification of Bao emphasizes the concepts of peripheral expansion and tight engagement with the aperture in the anulus, and of sealing from within the aperture using an engaging force. This stands in distinction to Applicant's approach.

As amended, the claims clarify that the device is constructed to span the aperture subannularly with substantially no trauma to the annular aperture. Applicant relies on subannular contact with the annulus to bridge the aperture, rather than biased contact (*i.e.*, circumferential sealing) with the aperture *per se* as described in Bao.

In light of the above, it is respectfully submitted that the independent claims are patentable over Bao and that the rejection should be withdrawn.

The dependent claims are allowable for the same reason as the independent claims from which they depend. Accordingly, it is respectfully submitted that the rejections of the dependent claims 50-53, 55, 56, 62, 67-69, 79, and 80 should be withdrawn.

Rejection under 35 U.S.C. § 102 [Lambrecht]

Claims 49-64, 67-71 and 75-88 stand rejected as anticipated by Lambrecht (US 6,425,919). Lambrecht (US 6,425,919) bears a filing date of June 30, 2002, claiming priority to August 18, 1999. As a preliminary matter, it will be useful to sort out the priority of the claimed subject matter.

Applicant's invention claims benefit of priority to October 20, 1999. Lambrecht (US 6,425,919) bears a filing date of June 30, 2000, and claims priority from three provisional applications. Lambrecht's first provisional was filed August 18, 1999, which is before Applicant's priority filing date. The remaining two provisionals were filed by Lambrecht on October 25, 1999 and December 21, 1999, both of which are after Applicant's priority filing date. It is pointed out here that the '919 patent specification is the result of a combination of these three provisional applications, and additional material added upon filing on June 30, 2000. These applications varied in scope and disclosure. It is important to note that only the material filed on August 18, 1999 may be considered prior art against the Applicant's originally-filed subject matter. Attached hereto are copies of Lambrecht's priority provisional applications 60/149,490 filed August 18, 1999, 60/149,490 filed October 25, 1999 and 60/172,996 filed December 21, 1999.

The table below depicts the basis for the rejection of the claims set forth in the rejection (referring to Lambrecht's omnibus '919 patent), and where the relied-upon teachings find priority in Lambrecht's provisional filings.

Bases for Rejection under §102(e)	Lambrecht Provisional Basis	Prior Art under §102(e)?
Figures 29B-29C	Figs. 12B-D, USPAN 60/172,996, filed 12/21/1999	NO

As can be appreciated from the above table, Lambrecht does not enjoy any priority to the subject matter relied upon for the rejection. Accordingly, Lambrecht can not be relied upon to reject independent claims 49 and 86-88. Because the rejection relies entirely upon teachings found in Lambrecht '919 that are not prior art to Applicant's invention, further treatment of the other limitations of the dependent claims is not necessary.

In light of the above, it is respectfully requested that the rejection be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 62 and 63 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao in view of Lambrecht. Claim 62 as amended recites that the claimed devices are flexible and resilient. It is respectfully submitted that claim 62 is allowable for the same reasons as the parent claim. Claim 63 has been canceled, and therefore the rejection is moot. Applicant reserves the right to reintroduce this and other canceled claims in future prosecution without

prejudice. It is respectfully submitted that one having ordinary skill in the art would appreciate that flexible resilient materials usable in the present invention would include shape memory materials, which are well known in the art.

Claims 72-74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao in view of Ferree. The rejection states that Bao discloses all limitations except for the use of autograft, allograft or xenograft. Without commenting on the correctness of the Examiner's conclusion that Ferree's disclosure of natural materials teaches the use of autograft, allograft or xenograft as required by the claims, nor the propriety of combining the plugs of Bao with the invention of Ferree, it is noted that the rejection under Bao has been overcome with respect to independent claim 49, from which these claim depend, and that the limited teachings of Ferree relied upon by the Examiner do not cure the inadequacies of Bao. Accordingly, it is respectfully requested that the rejection be withdrawn.

Claims 65 and 66 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lambrecht in view of Felt (WO 98/20939) and claims 72-74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lambrecht in view of Ferree. These rejections are traversed on the same grounds as articulated under the previous section *supra*. The teachings of Lambrecht relied upon for this rejection are not prior art, and the teachings of Felt and Ferree relied upon for this rejection do not cure the fatal defects of Lambrecht. It is respectfully requested that the rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW
GARRETT & DUNNER LLP

Dated: March 24, 2004

By: _____
Eric P. Raciti
Reg. No. 41,475

Attachments:

Exh. 1: Copy of Pease (US 2,671,444)
Exh. 2: Copy of Gan (US 5,964,807)
Exh. 3: Copy of Vas-Cath Inc. v. Mahurkar
Exh. 4: Copy of Ex parte Porter
Exh. 5: Copy of USPAN 60/149,490
Exh. 6: Copy of USPAN 60/161,085
Exh. 7: Copy of USPAN 60/172,996